

# Notice of Allowability

Application No.

10/088,750

Examiner

Chih-Min Kam

Applicant(s)

NAKASHIMA ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/21/06.
2. ☒ The allowed claim(s) is/are 9,16,17,20,22,23,25,27,30 and 32.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20060803.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 9, 16, 17, 20, 22, 23, 25, 27, 30 and 32 are pending.

Applicants' amendment filed on July 21, 2006 is acknowledged. Applicants' response has been fully considered. Claims 20, 23 and 30 have been amended, claims 1-4, 12, 14, 18, 19, 24, 28, 29 and 31 have been cancelled, and a new claim 32 has been added. Thus, claims 9, 16, 17, 20, 22, 23, 25, 27, 30 and 32 are examined.

### **Withdrawn Claim Objections**

2. The previous objection to claims 16, 22, 23 and 25 is withdrawn in view of applicant's amendment to the claims in the amendment filed July 21, 2006.

### **Withdrawn Claim Rejections - 35 USC § 112**

3. The previous rejection of claims 9, 17, 24, 27, 30 and 31 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment to the claims, applicants' cancellation of the claims, and applicants' response at pages 7-8 in the amendment filed July 21, 2006.

### **Examiner's Amendment**

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Luke A. Kilyk on August 3, 2006.

#### **Examiner's Amendments to the Claims:**

Claims 20 and 30 have been amended as follows.

20. (Currently amended) A method for synthesizing a heterologous protein or a

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heterologous polypeptide comprising the steps of

providing a cell-free protein expressing system,

providing a polynucleotide encoding the heterologous protein or heterologous polypeptide and a polynucleotide that promotes translation activity, wherein the polynucleotide that promotes translation activity has an RNA higher-order structure including PK (pseudoknot) I, II, and III structures and is selected from:

1) one of the base sequences of SEQ ID NOs: 1-7;

2) a base sequence of SEQ ID NO: 1, except that positions 187-188 of the base sequence of SEQ ID NO: 1 are cc instead of uu and positions 159-160 are gg instead of aa; and

3) a base sequence containing the base sequence of 1) or 2); and

wherein the polynucleotide encoding the heterologous protein or heterologous polypeptide is immediately downstream from the PKI structure of the polynucleotide that promotes translation activity, and

translating the polynucleotide encoding the heterologous protein or heterologous polypeptide in the cell-free protein expressing system to form the heterologous protein or heterologous polypeptide, wherein the translating is initiated and/or promoted by the polynucleotide that promotes translation activity, and

isolating the heterologous protein or heterologous polypeptide.

30. (Currently amended) A method for initiating synthesis of an arbitrary heterologous protein or heterologous polypeptide from an arbitrary codon which comprises the steps of

providing a cell-free protein expressing system,

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providing a polynucleotide encoding the arbitrary heterologous protein or heterologous polypeptide and a polynucleotide that promotes translation activity, wherein the polynucleotide that promotes translation activity has PK (pseudoknot) I, II, and III structures in a RNA higher-order structure having a function for promoting a translation activity, wherein the polynucleotide encoding the heterologous protein or heterologous polypeptide is immediately downstream from the PKI structure of the polynucleotide that promotes translation activity and wherein the RNA higher-order structure has a base sequence selected from:

- 1) one of the base sequences of SEQ ID NOs: 1-7;
- 2) a base sequence of SEQ ID NO: 1, except that positions 187-188 of the base sequence of SEQ ID NO: 1 are cc instead of uu and positions 159-160 are gg instead of aa; and
- 3) a base sequence containing the base sequence of 1) or 2);, and

translating the polynucleotide encoding the arbitrary heterologous protein or heterologous polypeptide from an arbitrary codon in the cell-free protein expressing system to form the heterologous protein or heterologous polypeptide, wherein the translating is initiated and/or promoted by the polynucleotide that promotes translation activity, and

isolating the heterologous protein or heterologous polypeptide.

The following is an **Examiner's Statement of Reasons for Allowance**:

The following reference appears to be the closest art to the claimed invention. Sasaki *et al.* (J. Virology, 73, 1219-1226 (1999)) disclose AUG-unrelated translation initiation is mediated by the internal ribosome entry site (IRES) of an insect picorna-like virus (i.e., *Plautia stali* intestine virus (PSIV)) *in vitro*, e.g., the LUC gene was efficiently translated when fused downstream of nt 6201 (pCAT-IRES<sub>6201</sub>-LUC) and nt 6264 (pCAT-IRES<sub>6264</sub>-LUC) *in vitro*, however, the reference does not teach the LUC gene is immediately downstream from the PKI structure of

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the polynucleotide that promotes translation activity (i.e., the PKI structure ends at nt 6192). Therefore, the claims are allowable over the art of record. The specific mutation of SEQ ID NO:1 (i.e., SEQ ID NO: 1 having cc instead of uu at positions 187-188, and gg instead of aa at positions 159-160) is disclosed in Fig. 8A (IRES (wild type) having aa at nt 6163-6164 and uu at nt 6191-6192; and IRES' (mutated) having gg at nt 6163-6164 and cc at nt 6191-6192) and page 16 of the specification.

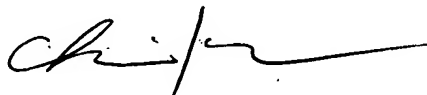
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



primary **CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK  
August 3, 2006